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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,092	09/22/2005	Ana Velasco Iglesias	13566.105008	7526
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KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER				
ROBINSON, HOPE A				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
04/02/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/540,092

Applicant(s)

VELASCO IGLESIAS ET AL.

Examiner

HOPE A. ROBINSON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4, 7, 18-22, 24-27, 29, 32-34, 43 and 46-54 is/are pending in the application.
- 4a) Of the above claim(s) 29, 33 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 21, 22, 24-27, 46 and 47 is/are rejected.
- 7) ☒ Claim(s) 2, 4, 18-20, 32, 43 and 48-54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21, 2009 has been entered.

Claim Disposition

2. Claims 2, 4, 7, 18-22, 24-27, 29, 32-34, 43 and 46-54 are pending. Claims 2, 4, 7, 18-22, 24-27, 32, 43 and 46-54 are under examination.

Claim Objections

3. Claims 1, 4, 19, 20, 22, 26, 43 and 46-54 are objected to because of the following informalities:

For clarity and precision of claim language, claim 1 should be amended to read,

- a) the nucleic acid sequence of SEQ ID NO: 1;
- b) the sacABCDEFHG operon of SEQ ID NO: 1;
- c) the sacA, sacB, sacC, sacD, sacE, sacF, sacG, sacH, genes SEQ ID NO: 1;

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d) a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO: 2, 3, 4, 5, 6, 7, 8 or 9; or

e) a nucleic acid sequence that is the full complement of the sequence in a), b), c) or d).

The dependent claims hereto are included.

Claims 4, 43 and 52 are objected to because the claim does not further limit claim 2.

For clarity and precision of claim language it is suggested that claims 19 and 20 are amended to recite "The vector of claim 18" in lieu of according to claim 18.

For clarity and precision of claim language it is suggested that claim 22 is amended to read, "a recombinant host cell transformed with the vector of claim 18".

Claim 26 should be amended to read, "A recombinant bacterial host cell transformed with the nucleic acid of claim 2...", for clarity.

For clarity it is suggested that claims 46-47 are amended to read, "The nucleic acid sequence of claim 2, further comprising...".

For clarity claims 48-51 should be amended to read, "the nucleic acid of claim 46 or 47 wherein..."

For clarity and precision of claim language, claim 53 should be amended to read,

a) the nucleic acid sequence of SEQ ID NO:1;

b) the sacABCDEFGH operon of SEQ ID NO:1;or

c) a nucleic acid sequence that is the full complement of the sequence in a) or b). The dependent claims hereto are included.

For clarity it is suggested that claim 54 is amended to spell out the species name of the organism.

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7, 21-22 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to "a nucleic acid" (i.e. of the sacABCDEFHG operon) of SEQ ID NO:1 wherein the nucleic acid encodes any peptide synthetase, L-tyr derivative hydroxylase, L-Tyr derivative methylase, and any safracin resistance protein. In addition, the claims recite a host cell and there is no indication of what organism and claim 25 recites a bacterium, however, no specific one is given. The claims are also drawn to a safracin analogue (see for example claim 26). Thus the claimed invention

encompasses a genus of analogues, derivatives and organisms which are not adequately described.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials'. *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or

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disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Further, no relationship between the disclosed species and the structures of the other proposed species is described. Thus, one of skill in the art would be unable to predict the structure of other members of this genus based on the instant disclosure. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 46-47 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 46-47 lack clear antecedent basis because they recite members of a Markush group that are not present in the independent claim. It is suggested that the language is amended to read, "further comprises". remain indefinite for the recitation of "stringent conditions" absent specific hybridization conditions because it is unclear what

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values to equate with that terminology since the art recognizes that hybridization conditions can vary, especially the wash conditions. Thus, the metes and bounds is unclear.

Response to Applicant's Arguments:

6. The response has been considered in full. Note that all rejections/objections of record have been withdrawn. Thus, applicant's comments are moot. Note however, that new objections and rejections have been instituted for the reasons set forth above.

Conclusion

7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652